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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,163

02/07/2005

Alastair Douglas Wright

NGP0024

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832

7590

02/03/2009

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EXAMINER

PATEL, PRITESH ASHOK

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

02/03/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,163	<b>Applicant(s)</b> WRIGHT, ALASTAIR DOUGLAS	
	<b>Examiner</b> PRITESH PATEL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/07/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show how a blocking portion is dislodged and needle is taken into a barrel as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

Art Unit: 3763

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-14 and 18-21 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Shaw (US 5385551) in view of Redfern et al. (US 5843034).

Concerning claims 1, 2, and 4, Shaw discloses a hypodermic syringe (10), capable of being filled with a substance, adapted for use with a retractable-type needle (34), and a piston member including a rim portion (42) mounting a dislodgeable blocking portion (72) (Fig 1 and 4). Shaw discloses a seal (46), but fails to disclose a seal covering a rim portion from interacting with a medicament. Redfern et al. discloses a seal (20) that is capable of covering a rim portion (Fig 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Shaw's seal with an extension of the seal as taught by Redfern et al. to decrease chance of reaction with a medicament. It would have further been obvious to one of ordinary skill in the art at the time of the invention that plastic parts are commonly used in syringes and that a syringe

is generally pre-filled before use.

Concerning claim 3, Shaw discloses a severing of a blocking portion and a rim portion during retraction of a needle (Fig 1).

Concerning claim 5 and 6, it would have been obvious to one of ordinary skill in the art at the time of the invention that a rim portion could be overmolded on a blocking portion by an insertion technique as is common, however, because these are apparatus claims the technique or molding name by which a part or parts are manufactured have no bearing, only the structure as is disclosed above.

Concerning claim 7 and 8, Shaw discloses a biasing element (96) that drives the needle into a syringe and severs a blocking portion from a rim portion (Fig 4).

Concerning claim 9, 10, and 11, as disclosed above modified Shaw provides a seal covering the rim portion. It would have been obvious to one of ordinary skill in the art at the time of the invention to make a surface in contact with a medicament, or a seal, to be non-reactive so a device may be used properly.

Concerning claim 12, Shaw discloses a perimetral contact point (78) is located on a rim portion where a seal is located (Fig 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to make said contact point into a groove and have a corresponding surface on a seal.

Concerning claim 13, Shaw discloses a rod (24) that forwardly moves a piston member, disclosed above (Fig 1).

Concerning claim 14, as can be seen in Fig 1 of Shaw, a rim portion is adapted to locate a forward portion of a rod.

Concerning claim 18, Shaw discloses a hollow rod (24) as designated by space (40) (Fig 1).

Concerning claims 19 and 21, Shaw discloses a needle coupling member (column 4 lines 2-17). It would have been obvious to use a snap-fit engagement as well as it is common in the art.

Concerning claim 20, Shaw discloses a necked-down portion of a barrel of a syringe which is a dispensing outlet where a syringe may attach (Fig 1).

4. Claims 15-17 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Shaw in view of Redfern et al. in further view of Shaw 2.

Concerning claim 15-17, in addition to the above disclosure, Shaw 2 discloses a rod which rendered substantially inaccessible after a stroke, able to be made by a thumb, a rod cap hiding in a retainer from which a rod cannot be taken (claim 1 of Shaw 2 and Fig 4 elements 50 and 52).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRITESH PATEL whose telephone number is (571)270-7025. The examiner can normally be reached on Monday-Friday 7:30Am-5:00PM, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. P./

Examiner, Art Unit 3763

01/29/2009

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763